

### **REMARKS/ARGUMENTS**

In the Office Action, the previous new matter objection was withdrawn and the rejection of the claims as being anticipated by Bykova was not remained. The remaining rejection will be responded to below.

a. Response to rejection of claims as being anticipated by Greenberg.

In the Office Action, claims 18 and 21-23 were rejected under 35 USC §102(b) as being anticipated by Greenberg. The rejection was maintained for reasons on record, i.e., that "Greenberg teaches the administration of reserpine to rats (patient) for the treatment of neurodegenerative conditions such as aging." (Office Action dated 26 July 2002). In response to Applicant's previous arguments that Greenberg failed to teach a method of therapeutic treatment, the Examiner maintained that "Greenberg clearly teaches the "chronic treatment" of rats with monoamine oxidase-A agonist (reserpine) which is a therapeutic treatment method."

For the reasons explained below, Applicant respectfully traverses the rejection.

In this and preceding Office Actions, the rejection has been based on only an abstract of the Greenberg reference. Applicant has now obtained the full text of the article, a copy of which is attached hereto (Attachment A). A reading of the complete reference shows that Greenberg in fact does not teach a method of therapeutic treatment using reserpine. Moreover, to the extent that the reference is relevant to therapeutic methods at all, it would suggest against the use of reserpine to treat "neurological conditions and effects of aging, as is required by Applicant's claims."

Greenberg states that the purpose of the reported investigations is to "provide more information on the relative ability of aged brain tissue to modify its adrenergic receptors in response to chronic changes in adrenergic input. To alter the adrenergic input, we have administered chronically, various psychoactive drugs known to effect brain adrenergic mechanisms; namely, reserpine..., desmethyl-imipramine (DMI),...and trifluoperazine,...". (Page 242, lines 10-18). Greenberg also compares information based on exposing the rats to light. In other words, Greenberg is not about therapeutic methods, but is instead simply an effort

to learn more about brain adrenergic actions by submitting the tissue to different drugs/agents and contrasting the results.

In point of fact, Greenberg expressly states that some of the rats were given reserpine for three days (the "chronic treatment") before being killed, while others were given only a single dose (the "acute treatment") and then killed 30 minutes later (pages 243-44 and FIG. 1). The brain tissues from the two groups of dead rats were then processed and analyzed for DNA binding. Despite the use of the term "treatment", it is clear that the reserpine is not administered to the rats in the manner of a therapy or for therapeutic purposes; as was noted previously, a "therapeutic treatment" is a treatment having a healing or curative effect. Here, the reserpine is simply administered (along with desmethyl-imipramine and trifluoperazine, plus exposure to light) in different ways to try to understand how the tissue works. Furthermore, Greenberg does not state or make any suggestion that its "treatment" could constitute a therapy or have a therapeutic nature.

Moreover, to the extent that Greenberg contains any suggestions relevant to therapeutic use of reserpine, it suggests against use of reserpine to treat the effects of aging. At pages 244-5, the reference states as follows: "To determine whether aged animals could exhibit the same adaptive response to reserpine as young rats, we compared specific DHA binding in various brain tissues from 3 and 24-month-old rats following chronic reserpine treatment. The results showed that aged tissue had an impaired ability to increase the number of adrenergic receptors in response to reserpine treatment i.e., in comparison with the reserpine response in young rats, the response in aged rats was decreased in cerebral cortex and abolished in cerebellum." In short, the reserpine was ineffective in the aged rats.

Greenberg further suggests that chronic administration of reserpine to aged individual would actually be undesirable, because of increased side effects and high lethality rates: "We also found that reserpine was much more lethal to the aged rats than to the young animals; whereas the young rats tolerated daily doses as high as 8 micromoles/kg, i.p., for several days, 15-75 percent of 24-month-old rats died after two days of treatment with doses of 2 or 4 micromoles/kg, i.p. increased side effects also have been noted in aged humans following reserpine treatment." (Page 245).

In summary, Greenberg teaches that reserpine is ineffective in the aged rats, and suggests that it is contraindicated in aged animals because its lethal effects.

In order to anticipate a claim, the reference must teach every element of the claim (MPEP 2131). For the reasons explained above, Greenberg fails to show a method for therapeutic treatment, as is expressly required by Applicant's claims. Instead, Greenberg describes an experiment in which reserpine (along with other psychoactive drugs/agents) is administered in different ways and the animal then killed to examine the effects on the tissues-no therapy or therapeutic method is disclosed. Moreover, Greenberg suggests against the use of reserpine to treat "neurological conditions and the effects of aging", as is also required by Applicant's claims, due to its side effects and high lethality when used on aged animals.

Accordingly, Applicant respectfully submits that Greenberg fails to anticipate Applicant's claims, and that the claims are patentably distinct and non-obvious thereover.

b. Conclusion

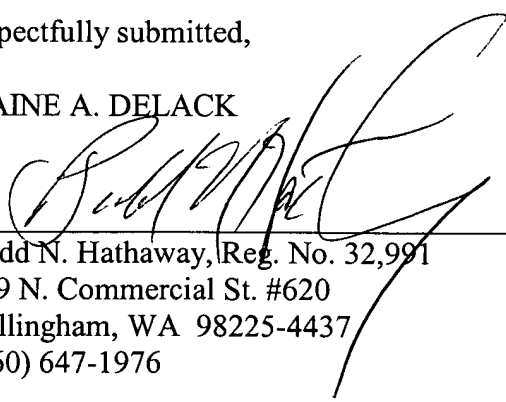
Applicant respectfully requests reconsideration of the present application in view of the remarks set forth herein. It is believed that the claims are now in condition for allowance. If there is any matter that can be expedited by consultation with Applicant's attorney, such would be welcome. Applicant's attorney can normally be reached at the telephone number given below.

Signed at Bellingham, County of Whatcom, State of Washington this 21st day of March 2005.

Respectfully submitted,

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